COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 02-VII-2007
C(2007)3302

NOT FOR PUBLICATION

COMMISSION DECISION

of 02-VII-2007

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(ONLY THE GERMAN TEXT IS AUTHENTIC)

COMMISSION DECISION

of 02-VII-2007

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Sanofi-Aventis Deutschland GmbH on 25 March 2007 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 24 May 2007,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3], and in particular Article 61(3) thereof,

Whereas:

(1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "Apidra - Insulin glulisine", which is entered in the Community Register of Medicinal Products under number(s) EU/1/04/285/001-036 and the placing on the market of which was authorised by

[1] OJ L 136, 30.4.2004, p. 1, Regulation as amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

Decision C(2004)3653 of 27 September 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2004)3653 accordingly.

(3) Sanofi-Aventis Deutschland GmbH submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(2004)3653 of 27 September 2004.

(4) The marketing authorisation should be updated, and Decision C(2004)3653 amended accordingly.

(5) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2004)3653 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/557/N/14	IIIB (EU/1/04/285/001-036)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III B is replaced by the text set out in Annex III B to this Decision.

[4] OJ L 311, 28.11.2001, p. 67, Directive as last amended by Regulation (EC) No 1901/2006 (OJ L 378, 27.12.2006, p.1).

Article 2

This Decision is addressed to Sanofi-Aventis Deutschland GmbH, Brueningstrasse, 50 - D 65926 Frankfurt am Main, Deutschland.

Done at Brussels, 02-VII-2007

For the Commission
Heinz ZOUREK
Director-General